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TO: **Examiner Manjunath N. RAO**
U.S. Patent & Trademark Office
Group Art Unit: 1652
Fax No: 1-571-273-0939

FROM: James E. Armstrong, IV
OF
ARMSTRONG, KRATZ, QUINTOS,
HANSON & BROOKS, LLP

RE: U.S. PATENT APPLICATION
SERIAL NO. **10/815,774**
Our Ref: 060911

Enclosure: **Executed Declaration**

NUMBER OF PAGES (INCLUDING THIS COVER SHEET): 4
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Date : March 29, 2007

Attny.Docket No.060911

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **YAMAGUCHI, Shotaro**

Serial No.: **10/815,774**

Group Art Unit: **1652**

Examiner: **RAO, Manjunath N.**

Filed: **April 2, 2004**

FOR: **NOVEL PROTEIN-DEAMIDATING ENZYME, MICROORGANISM PRODUCING THE SAME, GENE ENCODING THE SAME, PRODUCTION PROCESS THEREFOR, AND USE THEREOF**

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Shotaro YAMAGUCHI, a citizen of Japan, hereby declare and state:

I graduated from Graduate School, Faculty of Agriculture of Kyoto University with a Master's Degree in the field of Food Science and Technology in March of 1984.

In April of 1984, I was employed by Amano Pharmaceutical Co., Ltd. (Amano Pharmaceutical Co. has since changed its name to Amano Enzyme Co., Ltd.)

In January of 1992, I received a Ph.D. from Kyoto University.

From February of 1998 until March of 2001, I was a resident at the Institute of Food Research (Colney, Norwich NR4 7US, U.K.) as a visiting scientist.

Since April of 2001 up to the present I have been working at Amano Enzyme Co., Ltd.

Since 1984, I have been engaged in research and development of enzymes and their applications in the field of foods.

I am considered to be an expert in the field of the present invention. I am further fully knowledgeable of the disclosure of the present application (U.S. Patent Application No. 10/815,774) and the materials contained therein.

I am aware of the Office Action mailed October 24, 2006, in the above-identified application, wherein the examiner maintains the rejection of certain claims under 35 U.S.C. §112. Asserting that while the specification is enabling for a DNA with SEQ ID NO:5 or DNA encoding a protein having SEQ ID NO:6, with a protein deamidating activity as claimed, the specification is not enabling for any DNA which is 80% homologous to a DNA that encodes a polypeptide with SEQ ID NO:6 or hybridizes to a polynucleotide with SEQ ID NO:5 or a CDNA or genomic DNA which hybridizes, under stringent conditions, with the polynucleotide which has die nucleotide sequence of SEQ ID NO:5.

The examiner states that while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing the variants requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property.

The examiner asserts that without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all the virtually infinite possibilities.

In my opinion, the examiner's position is incorrect.

Specifically, the examiner is incorrect in asserting that one of ordinary skill in the art must be provided with guidance for the selection of which of the infinite numbers of variants have the claimed property. This is because the selection occurs by ruling out all sequences that do not have sufficient homology and/or that do not hybridize with the polynucleotide which has the nucleotide sequence of SEQ ID NO:5. This selection step narrows the remaining candidates to nucleotide sequences that are generally expected to encode an active enzyme. As evidence that my opinion is sound, note that the nucleotide sequence of the deamidation enzyme of the

present application (U.S. Application No: 10/815,774, related to *Chryseobacterium gleum* and that of related application No: 09/727,769, re *Chryseobacterium* sp. No. 9670 are about 76 % homologous. This is compelling evidence that percent homology is a sufficient basis on which to expect that nucleotide sequences having 80% homology with a nucleotide sequence encoding an active enzyme will also encode an active enzyme.

Furthermore, the hybridization method identifies DNA having nucleotide homology with the template DNA by utilizing the ability to form a double strand. Because this method utilizes the sequence actually obtained, SEQ ID NO:5, one skilled in the art would expect that sequences having a high homology can be obtained under stringent conditions.

This, having narrowed the sequences on the basis of homology, either directly or via hybridization, provides a pool of candidate polynucleotides that are expected to encode active enzymes. Screening this pool of polynucleotides for activity would not be undue experimentation, but rather routine.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, of both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 27th day of March, 2007

Shotaro Yamaguchi

Shotaro YAMAGUCHI